MDMA MEDICAL DEVICE MANUFACTURERS ASSOCIATION

September 10, 1998

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

Re: Docket No. 98N-0339
Public Meetings on Section 406(b) of the FDA Modernization Act of 1997

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA), a national trade association representing 130 manufacturers of therapeutic and diagnostic medical technologies, appreciates this opportunity to comment upon the Food and Drug Administration's (FDA's) initial step toward developing a plan to comply with the mandates set for the agency by section 406(b) of the FDA Modernization Act of 1997 (FDAMA).

MDMA applauds the agency for maintaining its dedication to consulting with its constituents frankly and cooperatively, and the association and its members trust that this spirit will continue to imbue the implementation of FDAMA. Moreover, we hope that this collaboration between the agency, its regulated industries, health professionals, and patients will result in further policy modifications that might go beyond the letter of FDAMA yet would still share the spirit of that landmark law. The FDA and its constituents -- most prominently the American public -- should consider FDAMA to be the first step in a series of improvements that will prepare the agency to meet our shared objectives in the promising century to come.

Turning to the questions on which the FDA has asked commenters to focus, MDMA will address each in turn.

(1) What can FDA do to improve its explanation of the Agency's submission review processes, and make explanations more available to product sponsors and other interested parties?

Through FDAMA, Congress clearly sought to promote greater interaction between product sponsors and the FDA, particularly in the premarket approval (PMA) process. The agency should follow this direction toward improved responsiveness to sponsor inquires for all categories of device submissions, not just PMAs. Specifically, MDMA urges the agency to apply to 510(k) submissions the ideals espoused by these FDAMA directives.

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To clarify the agency's processes for all categories and classes of medical devices, the Center for Devices and Radiological Health (CDRH) should publish a description of its internal device-evaluation protocols, including descriptions of how branch chiefs, division chiefs, and other Office of Device Evaluation personnel are generally involved in the review of product submissions. The protocols should be available on the FDA's World Wide Web site and for automated facsimile retrieval.

The FDA should also promote the availability of Device Advice, the self-service Internet-based information resource developed by the Division of Small Manufacturers Assistance (DSMA). Furthermore, the agency should encourage and empower DSMA to reach out to smaller manufacturers by holding outside-the-Beltway seminars on device submission requirements and other relevant topics. Smaller manufacturers have limited human and financial resources and often cannot afford to send their professional staff to Washington or Rockville for workshops. MDMA would be pleased to work with DSMA toward the development of programs that could be held in locations that are more accessible for smaller companies.

(2) How can the Agency maximize the availability and clarity of information concerning new products?

The agency could maximize the availability and clarity of new-product information by publishing information about recently cleared or approved products in a special section of the FDA's World Wide Web site. The listing could also include "hyperlinks" to each respective manufacturer's Web site. Just as the FDA's Web site is serving as a clearinghouse for information on the "year 2000" compliance of medical products, the agency's site could serve as the national repository for information on the latest innovations in medical technology.

MDMA trusts the agency will maximize the availability of information on new uses for existing products by fully implementing section 401 of FDAMA, which allows manufacturers to distribute peer-reviewed journal articles and related information about product uses that are not included in an approved product's labeling.

Finally, the agency should not over-react to the growth of product information on the Internet. FDA should allow all manufacturers to post information about their products on their World Wide Web sites. The FDA should certainly watch how the Internet is being used to promote products, but should not act too hastily or with preconceived notions to regulate this medium.

(3) How can FDA work with its partners to ensure that products -- domestic and foreign -- produced and marketed by the regulated industry are of high quality and provide necessary consumer protection; and how can FDA best establish and sustain an effective, timely, and science-based postmarketing surveillance system for reporting, monitoring, evaluating, and correcting problems associated with use/consumption of FDA-regulated products?

The regulatory burden on medical device manufacturers should always appropriately correspond

to the benefits that accrue from such regulations to the public health. Striking the appropriate balance between costs and benefits should be the goal of FDA's postmarketing surveillance program. For example, sections 211 and 212 of FDAMA, addressing device tracking and postmarketing surveillance, repealed the FDA's mandatory obligations in these areas and gave the agency discretionary authority to apply these controls. If the FDA uses its discretion wisely, the agency will be able to direct its limited resources toward watching those devices for which failure would likely result in significant harm to the patient.

The FDA should also move aggressively to implement a "sentinel" system for the reporting of deaths and injuries that may have been caused by misused or faulty products. While the establishment of such a system will require the allocation of significant up-front resources to the project, a well-run and well-analyzed "sentinel" system would be more efficient for the agency, should reduce costs for healthcare facilities, and could save millions of dollars in patient hospitalization costs and productivity losses.

(4) What approach should FDA use to ensure an appropriate scientific infrastructure with continued access to scientific and technical expertise needed to meet its statutory obligations and strengthen its science-based decision-making process?

The FDA needs adequate access to scientific and technical expertise to fulfill its obligations to the American people. However, this expertise does not have to be part of the agency's intramural infrastructure. By leveraging the resources of the scientific and technical experts outside the FDA, the agency can meet its statutory obligations and strengthen its science-based decision-making process without hiring scores of additional scientists. In MDMA's view, Congress sent this message to the agency through the FDAMA provisions on contracting and third-party review.

As an example, the federal government decades ago decided not to create a gigantic federal biomedical research enterprise, and instead chose to build a public-private partnership between the government and the nation's universities, medical schools, and teaching hospitals. Today, most of the funds appropriated to the National Institutes of Health (NIH) are spent in support of the biomedical and health services research conducted at universities and academic medical centers. The amount of intramural research conducted by NIH employees pales in comparison to the amount of high-quality extramural research carried out "under contract" to the NIH.

(5) What do you believe FDA should do to adequately meet the demands that are beginning to burden the application review process, especially for non-user fee products, so that it can meet its statutory obligations to achieve timely product reviews?

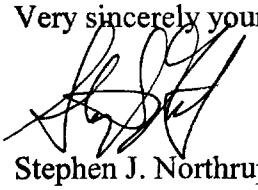
(6) What suggestions do you have for the Agency to eliminate backlogs in the review process?

To meet its statutory obligations to achieve timely product reviews and to eliminate backlogs in the review process, the FDA should focus its resources on its statutory obligations, and not on

other unilateral initiatives such as regulating tobacco. The agency should also take advantage of the tools provided by Congress through FDAMA, such as the authority to accredit third parties to review device submissions, to exempt additional class II devices from the 510(k) process, and to recognize self-certification of a device's conformance to national and international standards.

Once again, thank you for the opportunity to comment upon the FDA's initial step toward developing a plan to comply with the mandates set for the agency by the FDA Modernization Act.

Very sincerely yours,



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